2:30 p.m.

### 823-3 Effect of Intravenous Glycoprotein IIb/IIIa Receptor Antagonists on Survival in Percutaneous Coronary Interventions: A Meta-Analysis

Evangelia Karvouni, Demosthenes G. Katritsis, John P. Ioannidis, Athens Euroclinic, Athens, Greece, University of Ioannina School of Medicine, Ioannina, Greece

**Background.** Several randomized trials have shown that intravenous antagonists of the platelet glycoprotein IIb/IIIa receptor reduce the incidence of myocardial infarction (MI), and composite cardiac outcomes (death, MI or revascularization) in patients undergoing percutaneous coronary intervention (PCI). However, individual studies have not had adequate power to examine differences in mortality.
**Methods:** We performed a meta-analysis of 19 randomized placebo-controlled trials (20 comparisons, n=20,137) of intravenous glycoprotein IIb/IIIa receptor antagonists in patients undergoing PCI. Death was the primary outcome.
**Results:** Mortality was significantly reduced at 30 days (risk ratio [RR] 0.69 [95% CI, 0.53-0.90]), 6 months (RR 0.79 [95% CI, 0.64-0.97]), and including longer follow-up (RR 0.79 [95% CI, 0.66-0.94]) with no significant between-study heterogeneity. The relative risk reduction was largely similar in trials on patients with or without acute MI; in trials continuing or discontinuing heparin after the procedure; and in trials using stents or other PCI as the intended primary procedure. At 30 days and 6 months, MI and composite outcomes were significantly reduced ($P<0.001$ for all). Major bleeding was significantly increased only in trials where heparin infusion was continued after the procedure (RR 1.70 [95% CI, 1.36-2.14]), while there was no excess bleeding when heparin was discontinued (RR 1.02 [95% CI, 0.85-1.24]).
**Conclusion:** In patients undergoing PCI, glycoprotein IIb/IIIa receptor antagonists confer a significant, and sustained decrease in the risk of death.

2:45 p.m.

### 823-4 Prior Treatment With Statins Decreases Cardiac Biomarker Rise in Patients Undergoing Percutaneous Coronary Interventions

Sean Halligan, Joerg Hermann, Ryan Lennon, Geralyn Pumper, Stuart Higano, Verghese Mathew, David R. Holmes, Jr., Amir Lerman, Mayo Clinic-Rochester, Rochester, MN

**Background:** Statins have been shown to reduce primary and secondary cardiac events in patients with coronary artery disease. However, it is unclear what the mechanism is for this benefit in patients undergoing precutaneous coronary intervention (PCI); we sought to determine if statins reduce the post-PCI rise in cardiac biomarkers and postulated that this may be one mechanism for the observed benefit.
**Methods:** We reviewed 1498 patents from the Mayo Clinic Interventional Registry who underwent PCI during the years 2000 and 2001. Patients with recent myocardial infarction, shock, chronic renal disease or pre-procedural cardiac biomarker elevation were excluded. Patients were separated into two groups, Group 1 (n=752) consisted of patients on statins and Group 2 (n= 746) of patients not on statins prior to PCI.
**Results:** Prior to adjustment for baseline differences, Group 1 patients had a significantly lower rate of cardiac biomarker elevation post-PCI compared to Group 2 patients (n= 200 (27%) vs. n=236 (32%), p= 0.03). After adjusting for baseline differences, there were significantly fewer elevations in Troponin T levels (p=0.049) and a trend towards fewer elevations of any cardiac enzymes (p=0.056) post-procedure in Group 1. At follow up, unadjusted Kaplan-Meier curves indicate a significantly lower rate of death or myocardial infarction in Group 1 patients (p=0.012).
**Conclusions:** In this retrospective study, patients on statin therapy prior to PCI had a lower rise in cardiac biomarkers than those not on statin therapy. This maybe a mechanism for the cardiovascular benefits seen in patients on statins undergoing PCI.

3:00 p.m.

### 823-5 Clopidogrel Pretreatment Reduces Platelet Inflammatory Marker Expression in Patients Undergoing Percutaneous Coronary Intervention

Frank J. Zidar, Martin J. Quinn, Deepak L. Bhatt, Deepak P. Vivekananthan, Herbert D. Aronow, Stephen G. Ellis, Edward Plow, Eric J. Topol, The Cleveland Clinic Foundation, Cleveland, OH

**Background:** Inflammation is thought to play an important role in the pathogenesis of complications after percutaneous coronary intervention (PCI). Pretreatment with the platelet ADP receptor antagonist clopidogrel reduces ischemic complications after PCI. We examined the effect of clopidogrel pretreatment (>24 hours) on platelet inflammatory marker expression after PCI.
**Methods:** Patients undergoing elective PCI at the Cleveland Clinic were recruited into the study. Platelet and serum expression of the inflammatory markers CD40L and CD62P were compared in patients pretreated or not pretreated with clopidogrel. Blood was drawn before and after PCI. Platelet CD40L and CD62P expression in ADP (30 μM) and TRAP (5μM) activated samples were quantified by flow cytometry. Results are presented as the geometric mean fluorescence intensity of the platelet population minus the fluoresence of isotypic control antibody. Soluble CD40L levels were determined by ELISA.
**Results:** Complete data was available on 71 patients. 30 (42%) were pretreated with clopidogrel for a median of 5 days. Mean age was 68±11 years, 75% were male.

| Preprocedure | no pre-rx | clop. pre-rx | p value |
|---|---|---|---|
| CD40L (ADP) | 2.72 | 1.74 | p = .11 |
| CD40L (TRAP) | 5.18 | 4.06 | p = .42 |
| CD62P (ADP) | 196.01 | 75.71 | p = .0003 |
| CD62P (TRAP) | 274.51 | 166.00 | p = .024 |
| soluble CD40L | 1.21 | 1.08 | p = .85 |
| Postprocedure | | | |
| CD40L (ADP) | 2.75 | 1.26 | p = .14 |
| CD40L (TRAP) | 4.50 | 1.79 | p = .019 |
| CD62P (ADP) | 141.17 | 57.71 | p = .0002 |
| CD62P (TRAP) | 208.84 | 135.17 | p = .055 |
| soluble CD40L | 0.17 | 0.10 | p = .028 |

**Conclusions:** Clopidogrel pretreatment reduces platelet inflammatory marker expression, specifically CD62P, prior to and immediately after PCI. Pretreatment may also decrease levels of soluble CD40 after PCI. In addition to the known anti-platelet activity of clopidogrel, these anti-inflammatory effects may explain part of the clinical benefit of a clopidogrel pretreatment strategy.

3:15 p.m.

### 823-6 Benefit of Clopidogrel in Patients Undergoing Percutaneous Coronary Intervention in the CURE Trial Receiving and Not Receiving an Intracoronary Stent

Shamir R. Mehta, Madhu K. Natarajan, Thomas Wittlinger, Joao Morais, Matyas Keltai, Hans-Jurgen Rupprecht, Michel E. Bertrand, Keith A. Fox, Salim Yusuf, McMaster University, Hamilton, ON, Canada

**Background:** It is well established that patients undergoing percutaneous coronary intervention (PCI) receiving a stent benefit from treatment with clopidogrel, in addition to aspirin. In certain situations, it may not be possible to insert a stent. This analysis explores the consistency of benefit with clopidogrel in those patients treated with and without a stent.
**Methods:** In the CURE trial, patients were randomized to receive clopidogrel 300 mg loading dose, followed by 75 mg a day for up to one year or matching placebo, in addition to aspirin. The 2,552 patients undergoing PCI in the trial were divided into 2 groups: those receiving a stent and those not receiving a stent. Outcome events, cardiovascular (CV) death or myocardial infarction (MI), were analyzed in these groups to determine if there was consistency of benefit with clopidogrel.
**Results:** Overall, among the 2,552 patients undergoing PCI in the CURE study, there was a significant reduction in CV death or MI with clopidogrel compared with placebo (relative risk reduction 31%, P=0.002). 486 patients did not receive an intracoronary stent (253 placebo and 233 clopidogrel) and 2066 received at least one stent (1092 placebo and 1080 clopidogrel). Clopidogrel was beneficial both in those not receiving a stent (RRR 44%, P=0.028) and in those receiving a stent (RRR 27%, P=0.020) (Table).
**Conclusion:** In patients with ACS undergoing PCI, clopidogrel is beneficial in those treated with a stent, and in those receiving balloon angioplasty alone.

CV death or MI from randomization to end (up to 1 year)

| Group | Placebo | Clopidogrel | Relative Risk | 95% CI | P value |
|---|---|---|---|---|---|
| All patients | 169/1345 (12.6%) | 116/1313 (8.8%) | 0.69 | 0.54-0.87 | 0.002 |
| No Stent | 41/253 (16.2%) | 22/233 (9.4%) | 0.56 | 0.34-0.95 | 0.028 |
| Stent | 128/1092 (11.7%) | 94/1080 (8.7%) | 0.73 | 0.56-0.95 | 0.020 |

## POSTER SESSION

## 1127 Percutaneous Coronary Intervention and Outcomes

Monday, March 31, 2003, 3:00 p.m.-5:00 p.m.
McCormick Place, Hall A
Presentation Hour: 3:00 p.m.-4:00 p.m.

### 1127-187 The French Registry of Left Main Coronary Artery Treatment: Preliminary Results

Marc Silvestri, Thierry Lefèvre, Pierre Labrunie, Khalife Khalife, G. Bayet, Marie-Claude Morice, M. Bedossa, A. Chmait, On behalf of the FLM Registry Investigators, UCV, Marseille, France, Institut Cardiovasculaire Paris Sud, Massy, France

**Background:** CABG is the established treatment for unprotected left main coronary artery lesions (LMCA). However, PCI is now proposed as an alternative
**Methods:** A prospective registry was set-up in 11 high-volume French centers during 13 months to evaluate the outcome of pts with LMCA.

**Results :** From May 01 to June 02, 483 Pts were included, age 69±11 y, unstable angina 41%, 3 vessel disease 42%, distal LMCA 58%, EF 56±16%. They were classified as good candidates for surgery in 62%, poor in 33% and contra-indicated in 5%. Treatment was CABG in 48%, PCI in 40% and medical in 12%. Main characteristics were similar in the CABG and PCI groups except for an excess of poor candidates in the PCI group compared to surgery (45 vs 14%, p <0.001) and more RCA lesions in the CABG group (67 vs 43%, p<0.001). In the PCI group, Gp2b3a inhibitors were used in 21% and intra-aortic balloon pump in 9%. All Pts were stented on the LMCA (1.1±0.4 stents, diameter 3.8±0.3 mm, length 11.8±3.5 mm). Before stenting, rotational atherectomy was used in 7%, cutting balloon in 4% and balloon predilatation in 55% of cases. Angiographic success was obtained in all cases. LMCA MLD increased from 1.4±0.7 to 3.7±0.6mm. Stay was 15±21 days in the CABG group vs 5±3 in the PCI group (p<0.001). Mortality rate was as follows (preliminary):

**Conclusion:** Despite unfavorable characteristics, PCI for LMCA is associated with excellent 1-month and promising mid-term outcome compared to CABG. Complete 6-month follow-up will be presented at the meeting.

| | 1 month | 6 month | 12 month |
|---|---|---|---|
| PCI (n=183/102/31) | 0.5% | 3.6% | 4.1% |
| CABG (n=142/83/70) | 5.5%* | 6.4% | 7.2% |
| Medical (n=48/30/30) | 14.0%* | 22.0%* | 22.0% |

* p<0.05

## 1127-188 Can Tapered-Tip Guidewires Improve the Success Rate of Percutaneous Coronary Intervention in Chronic Total Occlusion?

Shigeru Saito, Shinji Tanaka, Saeko Takahashi, Yusuke Miyashita, Yoshitaka Hiroe, Shutaro Satake, SanQing Jia, Shonan Kamakura General Hospital, Kamakura, Japan, Beijing Friendship Hospital, Beijing, People's Republic of China

**Backgrounds:** Percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) is still technically challenging. The use of tapered-tip guidewires (Cross-it$^R$ or Conquest$^R$), which were specifically designed for CTO lesions, may improve the success rate of PCI in these lesions.

**Objectives and Methods:** In order to know whether the introduction of tapered-tip guidewires could improve the success rate, we retrospectively compared the results of PCI in CTO lesions in 182 patients during Phase I period (between April 1997 and December 1999) with those in 80 patients during Phase II period (between January and August 2001).

**Results:**

| | Phase I | Phase II | p |
|---|---|---|---|
| **No. of patients** | 182 | 80 | |
| **Male gender** | 78% | 83% | **NS** |
| **Age** | 65 +/- 11 | 67 +/- 8 | **NS** |
| **Triple vessel disease** | 21% | 20% | **NS** |
| **LVEF** | 49 +/- 18% | 49 +/- 13% | **NS** |
| **Duration of occlusion (months)** | 15 +/- 10 | 17 +/- 28 | **NS** |
| **Length of occlusion (mm)** | 17 +/- 5 | 18 +/- 6 | **NS** |
| **Tapered-type occlusion** | 33% | 35% | **NS** |
| **Contra-lateral angiography** | 20% | 23% | **NS** |
| **Use of hydrophilic guidewires** | 8% | 6% | **NS** |
| **Use of tapered-tip guidewires** | 0 | 60% | <0.001 |

The overall success rate was improved from 67% in Phase I to 81% in Phase II (p=0.019).

**Conclusions:** The use of tapered-tip guidewires can improve the success rate of PCI in CTO lesions.

## 1127-189 Adjunctive Porous Filter Protection From Distal Embolization in Primary Percutaneous Intervention for Acute Myocardial Infarction

Ugo Limbruno, Andrea Micheli, Anna S. Petronio, Caterina Palagi, Giovanni Amoroso, Marco De Carlo, Roberta Rossini, Daniele Carbocci, Paolo Caravelli, Vitoantonio Di Bello, Mario Mariani, University of Pisa, Pisa, Italy

**Background:** Effective reperfusion after primary percutaneous coronary intervention (PCI) in patients with acute myocardial infarction may be affected by distal embolization. We tested safety and feasibility of the adjunctive use of "Filter-wire Ex' (FW), a non-occluding porous filter device aimed to prevent distal embolism, during primary PCI on native coronary vessels.

**Methods:** Twenty-eight consecutive patients admitted < 6 hours after acute myocardial infarction onset were treated by primary PCI in association with FW to prevent distal embolism. Clinical outcome of these patients (group FW) was compared to 28 patients with acute myocardial infarction treated by primary PCI alone (group PCI) matched for age, sex and infarct location. Patients with cardiogenic shock, left main coronary artery disease, pre-PCI TIMI grade flow >1 in the infarct vessel or infarct vessel size < 3.0 mm were excluded from the study.

**Results:** Successful positioning of FW device was obtained in 26 out of 28 patients. All positioned FW were safely retrieved. Visible emboli in the FW basket were recovered in 8 patients (thrombus in 6 patients, plaque debris in 2 patients). Coronary dissections due to FW device positioning or retrieval were not ovserved. Use of FW was moderately time consuming (arterial puncture-to-vessel recanalization time in FW and PCI groups: 24±5 *vs* 20±5 min, $p<0.05$). A final Thrombolysis in Myocardial Infarction (TIMI) flow grade < 3 and persistent ST-segment elevation at the end of PCI were less frequent in the FW with respect to the PCI group (final TIMI flow grade: 4% *vs* 21%, *p*: N.S.; persistent ST-segment elevetion: 7% *vs* 36%, $p<0.05$). Moreover, patients in the FW group showed significantly lower peak creatin kinase-MB release (212±181 U/l *vs* 348±216 U/l, $p<0.02$) as well as greater improvement in left ventricular 2D-echo regional wall motion index at 4 weeks (-0.40±0.25 *vs* -0.21±0.26, $p<0.01$).

**Conclusion:** This is the first clinical study showing that the adjunctive use of the distal embolism protection device FW during primary PCI is safe and technically feasible, even in native coronary arteries. In this clinical setting, FW seems able to improve effective reperfusion.

## 1127-190 Gender-Based Differences in Long-Term Outcome Following Percutaneous Coronary Intervention

Jeffrey S. Berger, Babak A. Vakili, Timothy A. Sanborn, Warren Sherman, Kumar L. Ravi, David L. Brown, Beth Israel Medical Center, New York, NY

**Background:** Early studies suggested that morbidity and mortality following percutaneous coronary intervention (PCI) were greater in women than men. However, in recent reports, gender-related differences in short-term outcome have decreased as outcomes among women have improved. We sought to evaluate the effect of gender on long-term mortality among a large cohort of patients undergoing PCI in the contemporary era. **Methods:** Three hospitals in New York City contributed prospectively defined data elements on 4284 consecutive patients undergoing PCI in 1998-9. All-cause mortality at a mean follow-up of 3 years was the primary endpoint. **Results:** Of the 4284 patients, 1,331 (31%) were female. Females were significantly older than males (mean age 67 vs. 62 years, P<0.001) and less often white (72% vs.80%, P<0.001). Hypertension (78% vs. 66%, P<0.001) and diabetes (36% vs. 22%, P<0.001) were more prevalent in females. Prior cardiac surgery (14% vs. 19%, P=0.001) and previous myocardial infarction (MI) (33% vs. 36%, P=0.08) were less common among women. Presentation with unstable angina was more frequent in women (45% vs. 41%, P=0.034) whereas presentation with acute MI did not differ by gender. Congestive heart failure developed more commonly among women (7.1% vs. 4.1 %, P<0.001). The extent of coronary disease (one-, two- or three-vessel disease) did not differ between females and males. Mean ejection fraction was 52% in women and 50% in men (P<0.001). Stents were placed in 77% of both groups. Angiographic success was 97% for both women and men. In-hospital adverse outcomes including death, post-PCI MI, emergency bypass surgery, abrupt closure and stent thrombosis were uncommon and not different between groups. Mortality at 3 years was 10% for men and 8.9% for women (P=0.197). However, using Cox proportional hazards analysis to adjust for co-morbidities and possible confounders, female gender was associated with a significant independent reduction in the hazard of long-term mortality (Hazard Ratio, 0.775, 95% Confidence Interval, 0.620-0.969, P=0.025). **Conclusion:** Despite more high-risk charcteristics, female gender confers a long-term survival advantage following PCI.

## 1127-191 Predictors of New Renal Dialysis After Percutaneous Coronary Intervention

Beth A. Bartholomew, Srinivas Dukkipati, Kishore J. Harjai, Judith A. Boura, Datinder Deo, Michael W. Yerkey, H. Mehrdad Sadeghi, William W. O'Neill, Joel K. Kahn, William Beaumont Hospital, Royal Oak, MI

Background: Acute renal failure requiring hemodialysis (HD) is an infrequent but serious complication of percutaneous coronary intervention (PCI). The risk factors for HD have not been well elucidated in a large population.

Methods: We reviewed 31,397 PCI procedures in the William Beaumont Hospital PCI database from May 1993 to May 2002. Patients undergoing CABG surgery were excluded (n=338). We assessed the incidence and independent predictors of acute renal failure requiring HD.

Results: The incidence of HD was 0.3%. Characteristics predicting renal failure requiring HD are shown in the table. Interestingly, contrast volume over 150cc was not predictive of HD.

Conclusions: Renal failure requiring HD is infrequent with an incidence of 0.3%. Preexisting renal dysfunction remains the strongest predictor of new hemodialysis.

Predictors of Hemodialysis

| | P value | Odds Ratio | 95% CI |
|---|---|---|---|
| Creatinine Clearance <75ml/min | <0.0009 | 29.1 | 4.00-212 |
| Unplanned IAB P | <0.0001 | 5.54 | 3.01-10.2 |
| CHF | <0.0001 | 5.31 | 2.93-9.63 |
| Urgent PCI | 0.0009 | 4.90 | 1.92-12.5 |
| Diabetes | <0.0001 | 4.75 | 2.58-8.76 |
| Peripheral Vascular Disease | 0.026 | 1.93 | 1.08-3.44 |